Continuous Glucose Monitoring System

User Guide

GlucoRx AiDEX™

CE 0197

GlucoRx Ltd

Content

1. Important safety information

1.1 Indications for use

The GlucoRx AiDEX™ Continuous Glucose Monitoring System (CGMS) is indicated for continuous or regular monitoring of glucose levels in subcutaneous tissue, and is used for daily detection and self-management of blood glucose levels in people 14 years or older. It is intended for use by patients at home and in healthcare facilities. Interpretation of the GlucoRx AiDEX™ CGMS results should be based on the glucose trends and

several sequential readings over time. The GlucoRx AiDEX™ CGMS also aids in the detection of episodes of hyperglycaemia and hypoglycaemia. Measurements should not be used to make treatment adjustments, but rather as a reminder of when fingertip testing is required.

1.2 User group

This CGMS is suitable for people with diabetes who need regular blood glucose monitoring.

1.3 Contraindications

Patients who:

1. Suffer from alcoholism, drug abuse, severe

mental disorders (such as depression, schizophrenia).

2. Are unconscious.

3. Are unable to understand or master the usage of the device.

4. Have severe hearing or vision impairment.

5. Are below the age of 14 or are not capable of administering diabetes therapy themselves, or who always need to use CGMS under strict supervision of parents or qualified healthcare professionals.

1.4 Precautions

• CGMS readings should only be used as a reference for the supplemental monitoring of

diabetes mellitus and should not be used as a basis for clinical diagnosis.

• The CGMS should be completely removed before any Magnetic Resonance Imaging (MRI) scan.

• The CGMS contains small parts that can be dangerous if swallowed.

• Should there be rapid changes in blood glucose value displayed by the App (more than 0.1 mmol/L per minute or 1.8 mg/dL per minute), the displayed blood glucose levels may not be the same as the actual blood glucose levels. When the displayed blood glucose levels drop rapidly, the displayed value could be a higher-than-actual reading. When the displayed blood

glucose levels rise rapidly, the displayed value could be a lower-than-actual reading. When experiencing symptoms of hypoglycaemia or hyperglycaemia, please take a fingertip blood glucose test and do not rely entirely on the displayed reading on the App.

• Severe dehydration or excessive loss of water may result in inaccurate results. When you suspect you are dehydrated, consult a healthcare professional immediately.

• If you think the displayed reading on the App is inaccurate or inconsistent, please take a blood glucose meter test and use the result to calibrate the glucose sensor. If the problem persists, replace the sensor.

• While extensive user testing has been done on GlucoRx AiDEX™ CGMS in Type 1 and Type 2 diabetic patients, the study groups did not include women with gestational diabetes.
• The performance of the CGMS has not been evaluated when used with another implantable medical device, such as a pacemaker.
• Only compatible consumables should be used with the CGMS.
• If the product is not working properly or has been damaged, stop using it.
• When in a medical facility, the operator should wear gloves while using CGMS.
• Users of the CGMS App should have the basic skills needed to use Smartphones.
• The App currently does not have available

support for visually impaired users - Please do not use it if you are visually impaired.

• Any incident that is related to the App should be reported to GlucoRx.

• All pictures shown in this guide are for illustration purpose only. Actual product may vary due to product enhancement.

2. Product description

2.1 Component description

System Name:

GlucoRx AiDEX™ continuous glucose monitoring system

System configuration:

This product uses a GlucoRx AiDEX mobile App, a Transmitter and a Glucose Sensor.

The Transmitter package consists of the following components:

1 Transmitter

1 User Guide

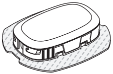
1 Quick Guide

The Sensor package consists of the following components:

1 Continuous Glucose Monitoring Sensor (Applicator with built-in sensor set)

1 User Guide Download Instruction

Transmitter

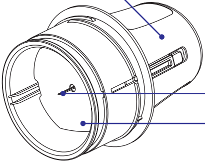


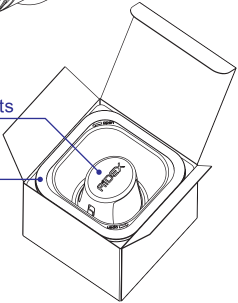
The transmitter is used together with the glucose sensor base. When the sensor and transmitter

are activated on the user's body, it measures and stores glucose readings as well as transmitting the readings to the GlucoRx AiDEX™ mobile App.

Sensor

The glucose sensor package contains a sterilised glucose sensor attached to a sensor base and a sensor applicator. The package is sterilised by gamma irradiation.


Sensor applicator
Glucose sensor
Sensor base tape


Sensor components
Sterile packaging

App

App name: GlucoRx AiDEX™ Continuous glucose monitoring App

Model

No.	Operating System	Unit	Release Version
RC2101	iOS	mg/dL	V1
RC2102	iOS	mmol/L	V1
RC2103	Android	mg/dL	V1
RC2104	Android	mmol/L	V1

Release version: V1

Blood glucose data measured by the CGMS is updated every 5 minutes. The App synchronises the sensor glucose data every 5 minutes.

The GlucoRx AiDEX™ App is compatible with the following devices: GlucoRx AiDEX™ CGMS

	GlucoRx Model No.	MicroTech Model No.
Sensor	GRX-SEN-S01	G7-S01
Transmitter	GRX-TRN-T01	G7-T01

GlucoRx/MicroTech Equivalent Model Numbers

3 User instruction

3.1 Software download and installation

3.1.1 Software download

You can download the GlucoRx AiDEX™ App from App Store (iOS) or Google Play (Android). Please check the Operating System (OS) on your phone to make sure you get the correct App version. To download the App, search "GlucoRx AiDEX" in App Store (iOS) or Google Play (Android).

Google play App Store

SEARCH GlucoRx AiDEX

3.1.2 Minimum requirements for software installation

iOS

Operating System (OS): iOS 10.0 and above
Memory: 2GB RAM
Storage: Minimum 200 MB
Network: WLAN (Wireless Local Area Network) or cellular network, as well as Bluetooth function

Android

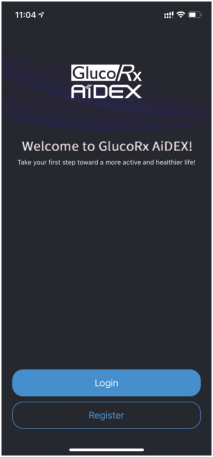
Operating System (OS): Android 8.0 and above
Memory: 3GB RAM
Storage: Minimum 200 MB Network: WLAN (Wireless Local Area Network) or cellular network, as well as Bluetooth function

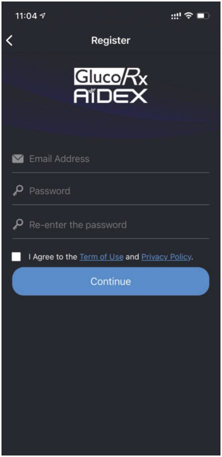
After finishing the download, the GlucoRx AiDEX™ App will be installed on your mobile device automatically.

3.2 Software registration, login and resetting

3.2.1 Software registration

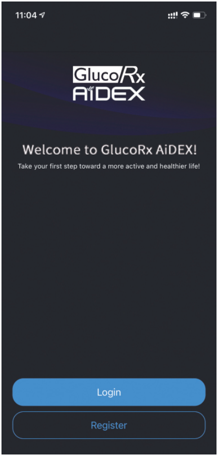
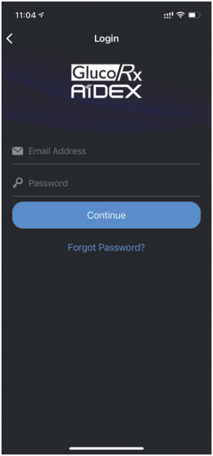
If you do not have an account, click "Register" button to enter the registration screen. Please input your email address and password. Read the Terms of Use and Privacy Policy before ticking the box. By ticking the box, you agree to comply with the Terms of Use and the Privacy Policy. Click "Continue" and you will receive a verification email. Follow the instruction in the email to complete your registration.


11:04
GlucoRx
AiDEX
Welcome to GlucoRx AiDEX!
Take your first step toward a more active and healthier life!
Login
Register


11:04
Register
GlucoRx
AiDEX
Email Address
Password
Re-enter the password
I Agree to the Term of Use and Privacy Policy.
Continue

3.2.2 Software login

Use your registered account email address and password to log in to the GlucoRx AiDEX™ App.


11:04
Welcome to GlucoRx AiDEX!
Take your first step toward a more active and healthier life!
Login
Register

11:04
Login
Email Address
Password
Continue
Forgot Password?

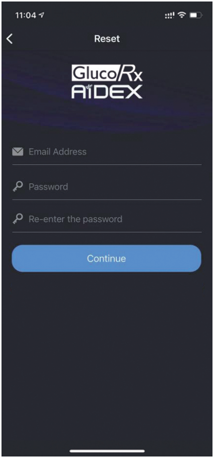
3.2.3 Password reset

If you forget your password, click “Forgot Password” to enter the password “Reset” screen.

Type in your email address and your new Password, then click “Continue”. You will receive a verification email. Follow the instruction in the email to complete your password reset.

Note

The new password and the old password cannot be identical.


11:04
Reset
GlucoRx
AiDEX
Email Address
Password
Re-enter the password
Continue

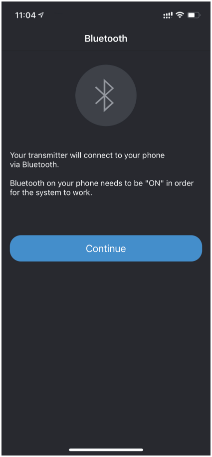
3.3 Introduction

When you log in to the GlucoRx AiDEX™ App for the first time, there will be an introduction guiding you to complete the basic system setups.

3.3.1 Bluetooth Setting

You will need Bluetooth connection to pair your CGMS transmitter. Click “Continue” to enable the Bluetooth connection between your CGMS and the App, or enable the Bluetooth in your phone settings.

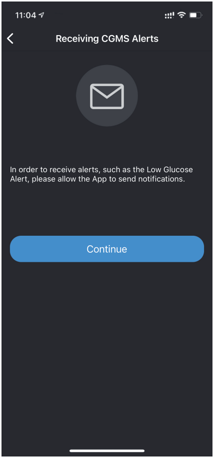
If you do not wish to enable the Bluetooth function, the App will not be able to pair with your CGMS to collect blood glucose data.


11:04
Bluetooth
Your transmitter will connect to your phone via Bluetooth.
Bluetooth on your phone needs to be "ON" in order for the system to work.
Continue

3.3.2 Notification

In the “Receiving CGMS Alerts” screen, choose “Continue” to enable the alert notification.

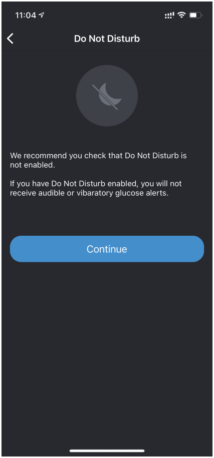
If you do not wish to receive alerts, you can disable the alert setting in “Settings”. Home > Settings > Alert Settings.


11:04
Receiving CGMS Alerts
In order to receive alerts, such as the Low Glucose Alert, please allow the App to send notifications.
Continue

3.3.3 Do not disturb

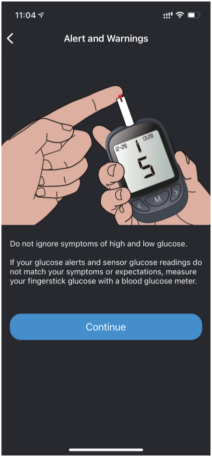
In the “Do Not Disturb” screen, reminder to check your “Do Not Disturb Mode” in your phone is displayed.

Ensure that your have turned off “Do Not Disturb Mode” in your phone before using the GlucoRx AiDEX™ App.


11:04
Do Not Disturb
We recommend you check that Do Not Disturb is not enabled.
If you have Do Not Disturb enabled, you will not receive audible or vibaratory glucose alerts.
Continue

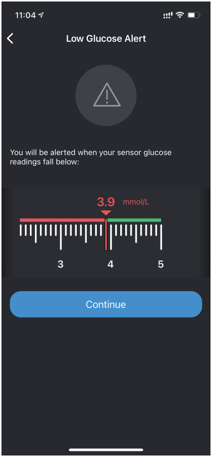
3.3.4 Alerts and warnings setting

In the “Alerts and Warnings” screen, there are tips for blood glucose management when alerts appear. If your glucose alerts and sensor glucose readings do not match your symptoms or expectations, take a blood glucose test with a blood glucose meter and consult your healthcare professional.


11:04
Alert and Warnings
12-28
13:28
M
Do not ignore symptoms of high and low glucose.
If your glucose alerts and sensor glucose readings do not match your symptoms or expectations, measure your fingerstick glucose with a blood glucose meter.
Continue

3.3.5 Low glucose alert setting

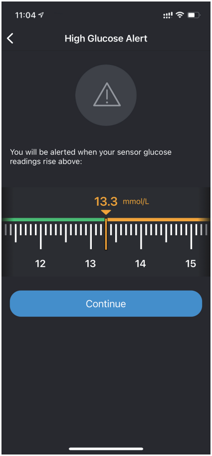
Set your lower glucose threshold in the low glucose alert setting screen. You can also change the alert threshold by clicking the "Settings" icon on the upper-right corner of the "Home" screen. Home > Settings > Alerts Settings.


11:04
Low Glucose Alert
You will be alerted when your sensor glucose readings fall below:
3.9 mmol/L
3
4
5
Continue

3.3.6 High glucose alert setting

After setting your low glucose alert, click "Continue" to enter the high glucose alert setting screen. Set your upper glucose limit in the high glucose alert setting screen.

You can also change the alert value by clicking the "Settings" icon on the upper-right corner of the "Home" screen. Home > Settings > Alerts Settings.


11:04
High Glucose Alert
You will be alerted when your sensor glucose readings rise above:
13.3 mmol/L
12
13
14
15
Continue

3.3.7 Connecting a transmitter

Click “Continue” to enter the “Transmitter” setting screen. Input the SN(Serial number) code on your transmitter package manually or scan the QR code on the transmitter package to complete the pairing automatically using the scan symbol ⛶ in the top right hand corner of the screen.


11:04
SN
XXXXXXXX
Continue
Skip

If you choose to skip the transmitter setting, you can also click the “Settings” icon on the upper-right corner of the “Home” screen and choose “Transmitter” to connect the transmitter.

Home > Settings > Transmitter

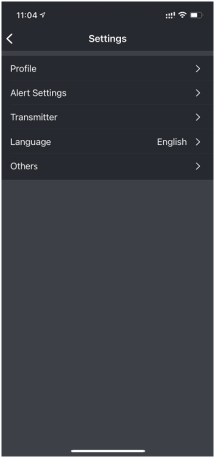
Please refer to chapter 3.4 for detailed operation procedures.

3.4 Application

3.4.1 Pairing a transmitter

The transmitter sends your continuous glucose data to the GlucoRx AiDEX™ App using Bluetooth wireless technology. You can manage your transmitter in the Home dashboard. Home > Settings > Transmitter.

Click the “Settings” icon on the top right-hand corner, then click “Transmitter”. Input the SN code manually or scan the QR code on the package to pair the transmitter using the scan symbol ⛶ in the top right hand corner of the screen.


11:04
Settings
Profile
Alert Settings
Transmitter
Language
English
Others


11:04
SN
XXXXXXXX
Continue
Skip


11:04
SN
XXXXXXXX


11:04
FFFFFF
Please pair Transmitter here.
Pair
Pairing

The pictures in this User Guide are for demonstration purpose only. Please pair your transmitter using the actual SN number.

Note

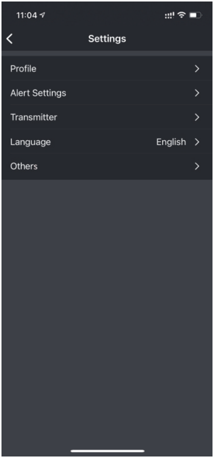
Please enable the Bluetooth function in your mobile device. The communication radius of your transmitter is 2 metres without obstacle. If pairing fails, a notification box will appear. Users may choose to input the serial number again. User may also choose to use the GlucoRx AiDEX™ App without pairing a transmitter by skipping this step.

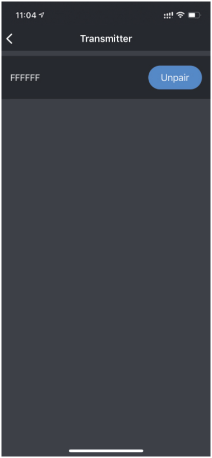
3.4.2 Unpairing a transmitter

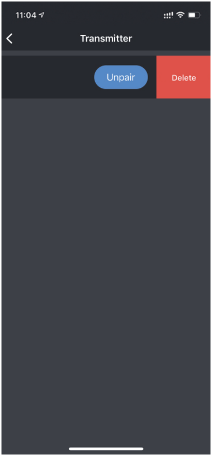
1. Click “Settings” icon on the top right-hand corner of the Home dashboard.
2. Click “Transmitter”.
3. Click the “Unpair” button. If unpairing fails, you can choose to delete the transmitter permanently.

Note

Please make sure the GlucoRx AiDEX™ App is paired with the transmitter before unpairing. If the transmitter is not connected to the App, you may delete the transmitter record permanently by clicking “Delete”.

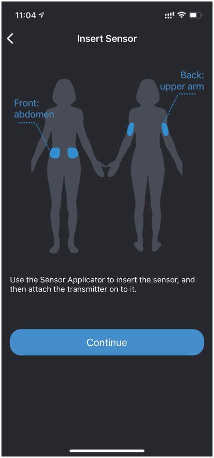

11:04
Settings
Profile
Alert Settings
Transmitter
Language
English
Others


11:04
Transmitter
FFFFFF
Unpair

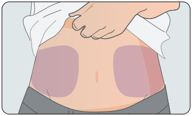

11:04
Transmitter
Unpair
Delete

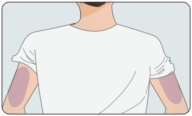
3.4.3 Applying a sensor

Use the sensor applicator of your CGMS to insert the GlucoRx AiDEX™ CGMS sensor. Please ensure the selected skin area is hair-free for best user-experience.

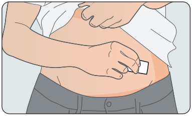

11:04
Insert Sensor
Front:
abdomen
Back:
upper arm
Use the Sensor Applicator to insert the sensor, and then attach the transmitter on to it.
Continue

Recommended areas for sensor application include the abdomen, the outside and the back of the upper arm. For best performance, avoid excessive motion which may weaken the sensor and its adhesive tape. It is strongly recommended to put the sensor on your abdomen rather than the arms or other areas. Rotate your sensor sites regularly to avoid discomfort or skin irritation. Please ensure you have already set up your GlucoRx AiDEX™ App following the instructions in chapter 3.1 to 3.3. of this User Guide. The

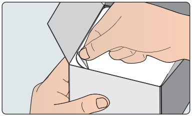




sensor will expire if you do not pair the sensor-transmitter set with your App within 30 minutes after application.



Before application, use alcohol pads to disinfect your selected skin area and wait for a minute to let the skin dry.

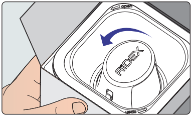


Open the sensor package.

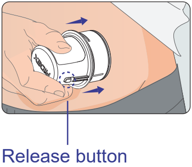
Note

Ensure the sensor has not expired by checking its expiration date. If the sensor has expired or the sterilised package is damaged, please do not use it.

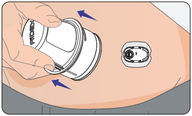
Take out the sensor applicator by turning it in an anti-clockwise direction.



Place the applicator on the top of your desired sensor site. Press it firmly against your skin and press the button to launch the sensor. After inserting the sensor, wait a few seconds to allow the sensor base patch to adhere to the skin.



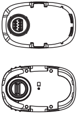
Remove the applicator. The sensor should be applied successfully.

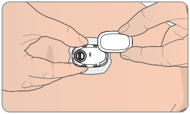


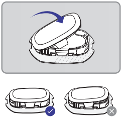
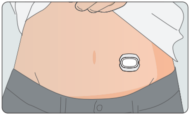
Note

Applying a sensor may cause bruising or bleeding. If bleeding does not stop, remove the sensor and apply a new sensor to a different location.

Align the transmitter to the sensor base and press the transmitter firmly onto it until it snaps onto the sensor base and attaches to it securely.





Note

If the transmitter is not matching the base as the picture shown above, the transmitter cannot function properly.

Note

Please use an over patch to reinforce th e adhesiveness if you think it is necessary.

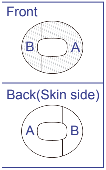
Over patch

To apply

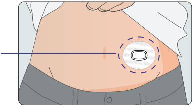
1. Clean skin area with a rubbing alcohol wipe and wait for a minute to dry.

2. Place tape over sensor without removing A or B.
3. Peel off section A and stretch gently over sensor. Smooth down on skin.
4. Remove section B and stretch gently over the rest of the sensor. Smooth down on skin.

Tips: Wait at least 20 minutes before swimming or athletic activities after application.



Over patch

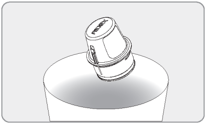

For illustration purposes
(Patch size and shape may differ)

To remove

1. Gently lift the over patch at the edge.
2. Slowly tug away the patch from the sensor.

For more support, contact UK customer care: info@glucorx.co.uk Tel: 0800 007 5892

The recyclable applicator is meant for single use only. Discard the used sensor package and sensor applicator according to your local disposal regulations.



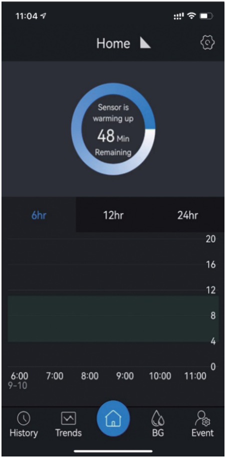
Follow the steps described carefully and be sure to only use components that are compatible. Use of unapproved components can result in injury.

3.4.4 Sensor warm-up

When you have successfully paired the transmitter, you need to wait for one hour for your sensor to warm up. You will see the real-time glucose readings (updated every 5 minutes) on the “Home” screen after sensor warm-up has finished.

Cautions: If you are using a new sensor for the first time, please click “New Sensor” in the pop-

up window that asks you to confirm that the GlucoRx AiDEX™ App is pairing with a new sensor. If the sensor is a used one, please click “A Used One”. If the sensor is a used one, you may skip the warm-up. The real-time glucose readings (updated every 5 minutes) will be displayed on the “Home” screen directly. In addition, please do not suspend or cancel the sensor warm-up before it is finished. Skipping sensor warm-up for new sensors can result in inaccurate blood glucose measurements and readings displayed on your App.


11:04
Home
Sensor is warming up
48 Min
Remaining
6hr
12hr
24hr
20
16
12
8
4
0
6:00
9-10
7:00
8:00
9:00
10:00
11:00
History
Trends
BG
Event

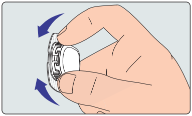
3.4.5 Removing a sensor

Remove the old sensor when the App indicates that the sensor has expired, or if you feel any site irritation or discomfort.

- Carefully pull the tape that holds the sensor to the skin from the edge and slowly uncover it until the entire sensor is removed. You can use warm soapy water to remove any remaining sticky residue.

- Press the two locking arms on one side of the sensor base, pull the transmitter away from the sensor base and then remove the transmitter so that it can be used again.

• The sensor is meant for single use only. Dispose the used sensor according to your local regulations.



3.5 GlucoRx AiDEX™ App functions

3.5.1 Home dashboard

Home dashboard displays the overview of your blood glucose levels.

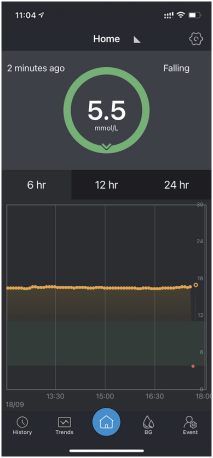
In the upper section of the dashboard, the real-time blood glucose level is displayed (updated every 5 minutes).

In the lower section of the dashboard, the blood glucose against time graph is displayed. You can select the time interval to see the glucose level history and trend in the past 6 hours, 12 hours or 24 hours.

Scroll the plot to view blood glucose levels over different periods. The data point gives you the blood glucose value and the time of measurement (updated every five minutes).

A pop-up notification box will appear two days before your sensor expires. When your sensor expires, the sensor status on the GlucoRx AiDEX™ App will also change to “expired”. Please replace the used sensor.

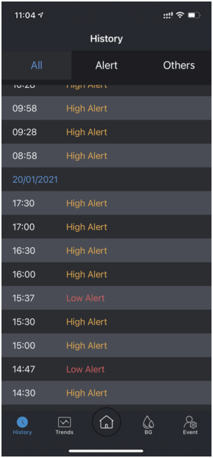

11:04
Home
2 minutes ago
Rising
5.5
mmol/L
6 hr
12 hr
24 hr
30
24
18
12
6
0
12:00
18/09
13:30
15:00
16:30
History
Trends
BG
Event


11:04
Home
2 minutes ago
Falling
5.5
mmol/L
6 hr
12 hr
24 hr
30
24
18
12
6
0
18/09
13:30
15:00
16:30
History
Trends
BG
Event

3.5.2 History dashboard

History dashboard displays glucose alert records, events, as well as glucose data in each day.

1. When the sensor blood glucose level is lower/higher than the pre-set alert value, the App will alert you every 30 minutes about your glucose levels. The alert and the time it took place is displayed in the History dashboard.
2. The events added on the “Home” screen will be displayed in the History dashboard.
3. The glucose levels recorded in the “Home” screen will be displayed in the History dashboard.
4. Click “All”, “Alerts” or “Others” to access different types of records.


11:04
History
All
Alert
Others
09:58 High Alert
09:28 High Alert
08:58 High Alert
20/01/2021
17:30 High Alert
17:00 High Alert
16:30 High Alert
16:00 High Alert
15:37 Low Alert
15:30 High Alert
15:00 High Alert
14:47 Low Alert
14:30 High Alert
History
Trends
BG
Event


11:04
History
All
Alert
Others
20/05/2021
19/05/2021
18/05/2021
17/05/2021
16/05/2021
15/05/2021
14/05/2021
13/05/2021
12/05/2021
11/05/2021
10/05/2021
09/05/2021
08/05/2021
History
Trends
BG
Event

3.5.3 Trends dashboard

The Trends dashboard displays the blood glucose analysis results.

In the top section, you can choose to display the analysis results over a certain period (Last 7 days, Last 14 Days, Last 30 Days or your customised interval).

In the "Average Glucose Level" section, your average sensor glucose level over a given period is displayed.

In the "Time in Range" section, the amount of time that you are in your pre-set target

glucose range is displayed. The number of hyperglycaemia and hypoglycaemia events and their corresponding durations are also displayed.

In the “Daily Trends” section, your blood glucose level recorded each day is displayed.

In the “Expand” section, the analysis parameters are displayed. Please contact your healthcare professional for interpretations.

Abbreviation	Interpretation
MGB	Mean Blood Glucose
M-value	Morbus value
SDBG	Standard Deviation of Blood Glucose
%CV	Percentage of Coefficient of Variation
J-index	An index that perpetuates the inclusion of standard deviation into the measurement of glycaemic variability
IQR	Inter-Quartile Range
AAC100	Area Above Curve 100
AUC100	Area Under Curve 100
LBGI	Low Blood Glucose Index
HBGI	High Blood Glucose Index
ADRR	Average Daily Risk Range
GRADE	Glycaemic Risk Assessment in Diabetes Equation
LAGE	Largest Amplitude of Glycaemic Excursions
MAGE	Mean Amplitude of Glycaemic Excursions
MAG	Mean Absolute Glucose Change (per hour)
MODD	Mean of Daily Differences
CONGA4	Continuous Overall Net Glycaemic Action (for 4h period)

Note

Please consult your healthcare professional for interpretation of the above parameters.

3.5.4 Blood glucose (BG) dashboard

In the Blood Glucose (BG) dashboard, you can calibrate the CGMS and record the reference blood glucose level for sensor calibration.

In the Blood Glucose dashboard, there are two functions for “Calibration” and “Recording”.

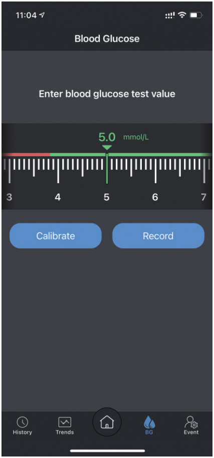
1. Click “Record” to enter the glucose value measured (from CGMS, blood glucose meter or by your healthcare professional). The record

will be displayed on the Home and History dashboard.

2. If the glucose value measured from other channels is different from the sensor glucose level displayed in the Home dashboard (percentage difference greater than 20%), you can manually input the calibration glucose level to calibrate the sensor. Alternatively, you can calibrate your sensor by clicking “Calibrate” in the suggested calibration automatic pop-up window.

Note

If you are pairing a new sensor, do not calibrate more than once in the first 6 hours after application. Do not calibrate the system frequently afterwards. Please calibrate only when your glucose value is stable. Do not calibrate while your blood glucose is rising or falling rapidly. The glucose value used for calibration should be the value measured no early than 5 minutes before the blood glucose test.


11:04
Blood Glucose
Enter blood glucose test value
5.0
mmol/L
3
4
5
6
7
Calibrate
Record
History
Trends
BG
Event

Scroll the slider to input your blood glucose test value. Once you have selected the right value, click "Calibrate" to complete the calibration.

3.5.5 Events dashboard

The GlucoRx AiDEX™ CGMS allows you to log and track events that may affect you blood glucose level.

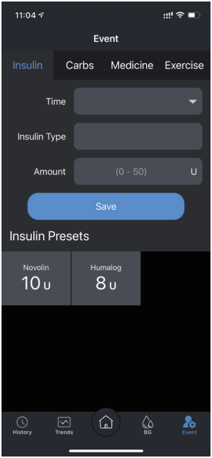
1. You can note down different types of events including “Insulin”, “Carbs”, “Medicine” and “Exercise” on the top of the Event dashboard.

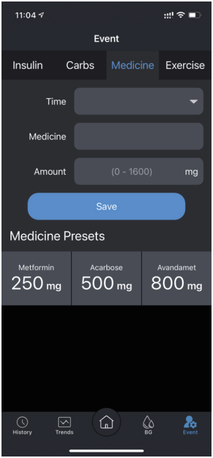
2. You can record the time that the event occurred.

3. The added events will be displayed in the History dashboard.

4. You can pre-set up to 9 events for quick recording.

5. The recorded events are uploaded to the Cloud Services. You can access the event history on the Cloud by using your GlucoRx AiDEX™ App account.


11:04
Event
Insulin
Carbs
Medicine
Exercise
Time
Insulin Type
Amount
(0 - 50)
U
Save
Insulin Presets
Novolin
10 U
Humalog
8 U
History
Trends
BG
Event


11:04
Event
Insulin
Carbs
Medicine
Exercise
Time
Medicine
Amount
(0 - 1600)
mg
Save
Medicine Presets
Metformin
250 mg
Acarbose
500 mg
Avandamet
800 mg
History
Trends
BG
Event

3.6 Alerts

3.6.1 Alert settings

In the Alerts dashboard, you can set up alerts. You can set the values for high glucose alerts, low glucose alerts and urgent low alerts. High glucose alerts and low glucose alerts will appear as pop-up notifications. The records of high glucose alerts and low glucose alerts will also be displayed in History dashboard.

1. You will be alerted by notification when:

· Your blood glucose is decreasing rapidly.

· Your blood glucose is increasing rapidly.

· Transmitter signal is lost.

Note

1. Before setting the alerts, please make sure the GlucoRx AiDEX™ App is paired with the sensor and transmitter.

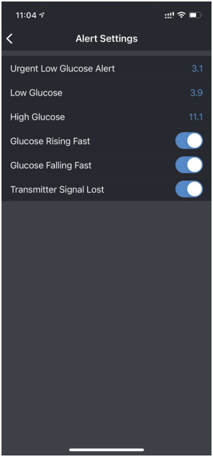
2. When low glucose alerts appear, please take a blood glucose test using a blood glucose meter and test strips. If the test result is not consistent with the blood glucose level displayed on the App, please contact your healthcare professional for advice.

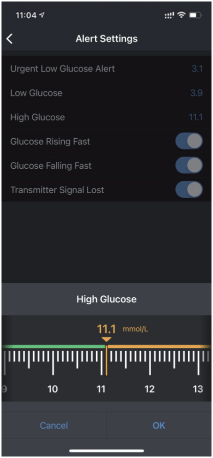
3. When high glucose alerts appear, please take a blood glucose test using your blood glucose meter and test strips. If the test result is not consistent with the blood glucose level displayed on the App, please

take medicine as advised by your doctor or inject insulin until your blood glucose level returns to normal glucose range.

4. When the sensor glucose level on average rises more than 0.1 mmol/L per minute, alert notification appears.

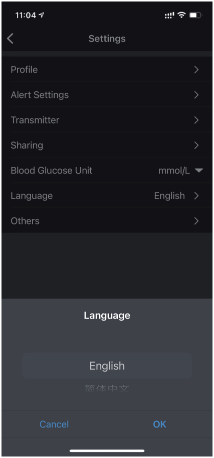
5. When the sensor glucose level on average declines more than 0.1 mmol/L per minute, alert notification appears.


11:04
Alert Settings
Urgent Low Glucose Alert 3.1
Low Glucose 3.9
High Glucose 11.1
Glucose Rising Fast
Glucose Falling Fast
Transmitter Signal Lost


11:04
Alert Settings
Urgent Low Glucose Alert 3.1
Low Glucose 3.9
High Glucose 11.1
Glucose Rising Fast
Glucose Falling Fast
Transmitter Signal Lost
High Glucose
11.1 mmol/L
10
11
12
13
Cancel
OK

3.7 Language

Click the "Settings" icon in the top right-hand corner, then click "Language" to select the GlucoRx AiDEX™ App display language.


11:04
Settings
Profile
Alert Settings
Transmitter
Sharing
Blood Glucose Unit
mmol/L
Language
English
Others
Language
English
简体中文
Cancel
OK

3.8 Others

3.8.1 Terms of service

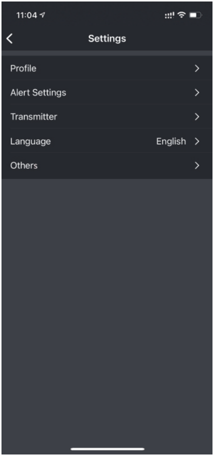
Under Home > Settings > Others > Terms of Service, you can check the Terms of Service of the GlucoRx AiDEX™ App.

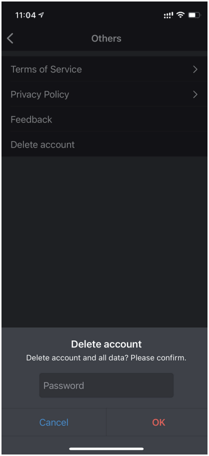
3.8.2 Privacy policy

Under Home > Settings > Others > Privacy Policy, you can check the Privacy Policy of the App.

3.8.3 Delete account

Click “Delete account” to permanently delete your account and all your relevent data stored in the server. Enter your password, then click “OK” to delete your account and personal data.


11:04
Settings
Profile
Alert Settings
Transmitter
Language
English
Others


11:04
Others
Terms of Service
Privacy Policy
Feedback
Delete account
Delete account
Delete account and all data? Please confirm.
Password
Cancel
OK

4. Maintenance

We pledge to continuously improve GlucoRx AiDEX™ App to improve customer experience. User feedback can be submitted to GlucoRx via customer care at info@glucorx.co.uk Tel: 0800 007 5892.

4.1 Caring for your Continuous Glucose Monitor System (CGMS)

Cleaning the transmitter

• Clean the outer surface of the transmitter using a mild detergent and a soft damp cloth. Use another cloth to dry.

• Disinfect the transmitter with an alcohol wipe.

• Do not use solvents, nail polish remover or

paint thinner to scrub the outer surface.

- Keep the transmitter dry.
- Do not apply any lubricant to the transmitter.
- Keep the connection port area clean.

Note

Do not immerse the transmitter in water or other liquids. Avoid dust, dirt, blood, chemicals, water and other substances on the transmitter connection port.

Disposal

Dispose transmitters and sensors that you do not use any more in compliance with local regulations for electronic devices, batteries, sharps and biohazardous materials. Please do not discard old products or accessories directly.

For further information on how to dispose of system components, please contact GlucoRx customer care.

Transportation

Avoid placing heavy weight on top of the transmitter. Avoid direct sunlight and rain.

Storage

If you are temporarily not using the transmitter or sensor system, store the components in a cool, dry, clean and well-ventilated area. If they fail, they need to be returned to the supplier for repair. No third-party individuals or organisations are allowed to perform repair.

Specifications

Item	Subcomponent	
	Transmitter	Sensor
Model number	GRX-TRN-T01 (G7-T01)	GRX-SEN-S01 (G7-S01)
Operating temperature	5 - 40℃（41-104 °F）	
Operating humidity	10-93%（non-condensing）	
Storage and transportation temperature	-20℃ - 60℃	4℃ - 30℃
Storage and transportation humidity	5-95%（non-condensing）	
Storage and transportation pressure	700hpa~1060hpa	
Ingress protection level	IPX7	
Use life	4 Years	GRX-SEN-S01: 14 days Shelf life: 1 year
Detection range	2.0 mmol/L-25.0 mmol/L	
Measurement accuracy	When the glucose concentration >4.2mmol/l (75mg/dL), the accuracy deviation of the sensor does not exceed ±20%; when the glucose concentration ≤4.2 (75mg/dL), the accuracy deviation does not exceed ±1mmol/l (18mg/dL).	
Wireless frequency and bandwidth	Frequency: 2.402GHz ～ 2.48 GHz Bandwidth: 1Mbps	
Wireless modulation	GFSK	
Radiated power	-2dBm	

4.2 Quality control test

You should perform a control solution test if you suspect that your blood glucose meter and/or test strips are not working properly, or if you suspect that your test results are inaccurate or inconsistent with how you feel.

5. Data security

The information stored in this GlucoRx AiDEX™ App includes:

- Blood glucose information.
- Personal information (e.g., name, gender, date of birth, etc.).
- Exercise patterns.
- Diets

- Medicine history
- Insulin injection history

The data collected is stored in a Cloud Service. The data is protected by cloud-based encryption and other security mechanisms offered by the cloud service provider. The data stored in the Cloud can only be interpreted using the decryption algorithm offered by the cloud service provider. User information can be protected. You can clear your data stored in the Cloud service by using the: “Delete account” function under Home > Settings > Others > Delete account. By doing so, you can permanently delete your data stored in the Cloud and your account.

6. Troubleshooting

Data Lost

The GlucoRx AiDEX™ App can recover data after restarting. After restarting, the saved App data will be restored automatically. All the saved but not displayed data can be displayed again. If the App fails to display blood glucose data, please restart the Bluetooth and re-pair the App and the corresponding transmitter or contact GlucoRx.

Transmitter Signal Lost

When "Transmitter Signal Lost" notification pops up, please check if you have turned off your Bluetooth. After turning on your

Bluetooth function, signal connection between the App and the transmitter will be restored automatically. If “Error” notification pops up, please restart the App. The blood glucose data is temporarily stored in the transmitter during signal loss. When connection between the App and the transmitter is restored, all relevant data will be transmitted to the App.

Fail to read data

Data reading failure can be caused by signal interference. Users are required to stay away from environments with strong electromagnetic interference, or contact GlucoRx.

7. Electromagnetic compatibility

In this chapter, “device” is defined as any component that requires electricity to function.

Transmitters and sensors (devices) are intended for use in the electromagnetic environment specified below. The user of the device should ensure that the device is used in such an environment.

Portable and mobile RF communication interference may have an impact on the device.

The device should not be used adjacent to or

stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Performance	Description
Measurement accuracy	When the glucose concentration is >4.2mmol/L (75mg/dL), the sensor accuracy deviation does not exceed ±20%; When the glucose concentration is ≤4.2mmol/L (75mg/dL), the accuracy deviation does not exceed ±20mg/dL

IEC60601-1-2 Table 201

Guidance and manufacturer's declaration – electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply.
Harmonic emissions IEC 61000-3-2	Class A	Move to a place within the normal operating temperature range and repeat the test.
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	Repeat test. If you see the same result, contact your healthcare professional immediately.

IEC 60601-1-2: Table 202

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC 60601-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient burst IEC 61000-4-4	±2KV power cord ±1KV input/output	±2KV power cord ±1KV input/output	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1KV line to GND ±2KV line to GND	±1KV line to GND ±2KV line to GND	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT for 0.5 weeks (>95% dip in UT) 40% UT for 5 weeks (60% dip in UT) 70% UT for 25 weeks (30% dip in UT) <5% UT for 5s (>95% dip in UT)	<5% UT for 0.5 weeks (>95% dip in UT) 40% UT for 5 weeks (60% dip in UT) 70% UT for 25 weeks (30% dip in UT) <5% UT for 5s (>95% dip in UT)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	The power frequency magnetic field should have the characteristics of power frequency magnetic field level at atypical place in a typical commercial and hospital environment

IEC 60601-1-2: Table 204

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3V(Vrms) 150kHz~80MHz 10V(engineering medical frequency band) 150kHz~80MHz	3V(Vrms) 10V (engineering medical frequency band)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz~800MHz $d=2.3\sqrt{P}$ 800MHz~2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10V/m 80MHz~2.5GHz	10V/m	

IEC60601-1-2: Table 206

Recommended separation distances between portable and mobile RF communications equipment and the device

These devices are intended for use in an environment in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference. Maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below (the maximum separation distance depends on the maximum output power of the transmitter).

Maximum rated output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

8. Explanation of symbols

This section explains the icons used on this CGMS:

Icon	Explanation
	Manufacturer information.
EC REP	Authorised representative in the European Community.
CE 0197	European Conformity / Comformité Européenne. This symbol suggests that the software has acquired European technical conformity in accordance with Directive 93/42/EEC.

	Class II equipment
	Single use only
	Type BF applied part
	Storage temperature
STERILE | R	Sterilised by radiation
	Refer to instruction manual/booklet
	Biohazard
IVD	In vitro diagnostic device
	Non-ionising radiation
	See instructions for use
IPX7	Water resistance level
	Consult instructions for use
	Do not use if package is damaged and consult instructions for use
	Humidity limitation
	Atmospheric pressure limitation
	Separate collection for EEE

MicroTech Medical

MicroTech Medical (Hangzhou) Co.,Ltd.
No.108 Liuze St., Cangqian, Yuhang District,
Hangzhou, 311121 Zhejiang, P.R.China
www.microtechmd.com

EC REP **Lotus NL B.V.**
Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.

GlucoRx
Distributor:
GlucoRx Ltd.
Unit 1C Henley Business Park
Pirbright Road, Guildford,
Surrey, GU3 2DX, United Kingdom

Customer Careline:
0800 007 5892
E-mail: info@glucorx.co.uk
Website: www.glucorx.co.uk

1016-PMTL-261. V02